REMARKS

Applicant has carefully reviewed and considered the contents of the Office Action dated May 22, 2002. Reconsideration is respectfully requested in view of the foregoing amendments and the comments set forth below.

By this Amendment, claim 13 has been cancelled and replaced with amended claim 20 and claims 14-17 and 19 are amended. Accordingly, claims 14-25 are pending in the instant application.

Claim 17 was rejected under 35 U.S.C. § 112, second paragraph as being indefinite for the reason set forth in paragraph 2 of the Action. By the foregoing amendment to claim 17, the phrase "at least memory" is changed to --at least one memory-- . That is, claim 17 refers to at least one memory structure. Accordingly, it is respectfully submitted that claim 17 is fully definite under 35 U.S.C. § 112, second paragraph and withdrawal of that rejection is requested.

Claims 13, 14, and 19 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,855,592 to McGee et al. (hereinafter refer to as "McGee") as explained in paragraph 3 of the Action. Claims 15, 17, and 18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over McGee in view U.S. Patent No. 5,834,031 to Cookston et al. (hereinafter refer to as "Cookston") as described in paragraph 5 of the Action. Claims 16, and 20-24 were rejected under 35 U.S.C. § 103(a) as being unpatentable over McGee in view of EP 0 601 328 to Ljungström as explained in paragraph 6 of the Action. Claim 25 was rejected under 35 U.S.C. § 103(a) as being unpatentable over McGee and Ljungström in view U.S. Patent No. 4,664,120 to Hess as outlined in paragraph 7 of the Action. These rejections are respectfully traverse.

As explained in the amendment filed February 28, 2002, Applicant's invention is directed to an electrode arrangement for endocardial discharge of defibrillation pulses in the atrium or a

ventricle of the heart. According to Applicant's claimed invention the electrode lead has an undivided proximal end, a distal end and a splitter from which two branches of the electrode lead extend to the distal end where each branch has a central core extending from the splitter of the electrode lead and the at least two branches include a septal branch and a lateral branch. The septal branch and lateral branch each have an equal number of electrically conductive surface portions disposed thereon and each electrically conductive surface portion of the septal branch is unambiguously associated with an electrically conductive surface portion of the lateral branch as recited in independent claim 20.

As a result of this claimed structure, the electrode lead according to the invention can assume positions in a heart so that associated electrodes in the septal and lateral branches can define layers, starting from the transition of the vena cava of the heart into the atrium thereof, thereby subdividing the atrium of the heart in parallel successive relationship (page 5, line 26 through page 6, line 3 of the instant specification). Further, such an electrode arrangement makes it possible for the atrium to be stimulated either successively in time-displaced relationship in a cascade-like procedure or simultaneously with bipolar voltage pulses. As a result, the claimed invention can achieve a defibrillation effect with an extremely low level of stimulation energy and provides defibrillation which can be substantially pain-free for the patient (page 6, lines 9-15).

McGee is directed to systems and methods for multi-site cardiac defibrillation using multiple electrode structures. While McGee discloses the use of a plurality of splines 22 on which a plurality of electrode 30 are disposed, McGee is silent as to how the electrodes 30 relate to one another. Nowhere does McGee disclose, teach or even suggest that an electrode can be associated with another electrode to define a layer in the atrium as claimed and described by

Applicant. Column 7, lines 20-34 of McGee discloses a pacing control algorithm 54 that commands the pacing module 52 to transmit pacing signals "to a selected one or more electrodes 30, or all the electrodes 30 at once" to capture and defibrillate the induced atrial defibrillation. Likewise, column 9, lines 55-65 of McGee teaches that the algorithm 54 delivers a first set a pacing pulses to the band of the most distal electrode on each spline element, then proceeds in sequence to adjacent bands of electrodes in succession toward the most proximal band of electrodes on the spline elements. Thus, McGee, at most, teaches delivering pulses to the most distal electrodes and not the claimed electrical conductive surface portions of the septal branch being unambiguously associated with an electrical conducted surface portion of the lateral branch. Accordingly, it is respectfully submitted that McGee fails to disclose or suggest the unambiguously associated electrically conducted surface portions, as well as "the lead configuration containing a septal branch and a lateral branch" as recognized in paragraph 6 of the Action.

The secondary reference to Ljungström is directed to a defibrillation system. However, contrary to the Action's position, Ljungström simply discloses an electrode head 17 comprising a number of leg-shaped parts 18, 19 that are connected to a conductor 10 of the electrode cable and function as defibrillation surfaces. Nowhere does Ljungström disclose, teach or suggest that the electrically conducted surface portions of a septal branch be unambiguously associated with the electrically conducted surface portion of a lateral branch as recited in independent claim 20. It appears that Ljungström, like McGee, discloses that a higher number of leg-shaped parts 18, 19 can be used on electrode head 17 and that these parts are attached evenly distributed on the distal end of the electrode cable. (See attached non-verified English translation of Col. 5, line 35 through Col. 6, line 23 of Ljungström). The Action refers to page and line numbers of the

Ljungström reference, but it is unclear to what passages these citations refer. Accordingly, clarification of the Action is requested.

Moreover, the attached English translation of a portion of Ljungström simply describes leg-shaped parts 18,19 being expanded to "fit themselves against the secondary heart wall, wherein defibrillation pulses can be emitted" (Page 1, lines 14-16 of English translation). Nowhere does Ljungström disclose that the structure of the leg-shaped parts, nor does Ljungström disclose, let alone teach or suggest that the electrode conductive surface portion of a lateral branch is to be unambiguously associated with an electrically conductive surface portion of a septal branch. Accordingly, it is respectfully submitted that Ljungström does not render the claimed invention obvious.

The Action applied Hess for its teaching of a lead configuration that contains two atrial electrode branches 16 and a ventricular branch 15 to provide a multifunctional lead. Nowhere does Hess disclose at least two branches including a septal branch and a lateral branch. Moreover, Hess failed to disclose, let alone teach or suggest the unambiguously associated electrically conductive surface portions of any two branches, let alone the claimed septal and lateral branches. Accordingly, Hess cannot render the claimed invention unpatentable.

Cookston is directed to an apparatus and method for deflecting a tip of a lead or catheter. Nowhere does Cookston address, let alone, disclose, teach or suggest an electrode lead having at least two branches including a septal and a lateral branch where electrically conductive surface portions disposed on a respective branch are unambiguously associated with an electrically conductive surface portion of the other branch. Accordingly, Cookston cannot render the claimed invention obvious.

It is respectfully submitted that this Amendment After Final Rejection places the application in condition for allowance, does not raise new issues (as claim 20 is amended to be in independent form) and does not raise the issue of new matter. Accordingly, Applicants respectfully request that this Amendment After Final Rejection be entered and that this application be passed to issuance.

Should the Examiner believe that a conference would advance the prosecution of this application, the Examiner is encouraged to telephone the undersigned counsel to arrange such a conference.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claim 13 has been replaced with amended claim 20 as follows:

20. (Amended) [The electrode arrangement according to claim 13,] An electrode arrangement for the endocardial discharge of defibrillation pulses in one of the atrium and ventricle of the heart, comprising:

an electrode lead having an undivided proximal end, a distal end and a splitter from which at least two branches of the electrode lead extend to the distal end, each branch having a central core extending from the splitter of the electrode lead, said central core being made of a memory member structure that enables good contact to be maintained between each branch and a wall of the atrium or the ventricle; and

a plurality of electrically conductive surface portions disposed on the at least two branches, said plurality of electrically conductive surface portions being electrically connected by way of the electrode lead to an electrical pulse-discharging device at the proximal end of the electrode lead, wherein the at least two branches include a septal branch and a lateral branch, and the septal branch and lateral branch each have an equal number of electrically conductive surface portions disposed thereon, and each electrically conductive surface portion of the septal branch is unambiguously associated with an electrically conductive surface portion of the lateral branch.

Claims 14-17, and 19 have been amended as follows:

14. (Amended) The electrode arrangement according to claim [13] 20, further comprising a sliding sleeve displaceable in a longitudinal direction of the electrode lead and actuating means for actuating the sliding sleeve wherein said central core is of one-piece

construction in the form of a spring element and causes the branches to split apart when the actuating means moves the sliding sleeve toward the proximal end of the electrode lead.

15. (Amended) The electrode arrangement according to claim [13] 20, further comprising a sliding sleeve displaceable in a longitudinal direction of the electrode lead, means for actuating the sliding sleeve to split the at least two branches apart, and means for heating the memory member structure so that the shape of the memory member structure can change to maintain good contact between each branch and a wall of the atrium or the ventricle.

16. (Amended) The electrode arrangement according to claim 15, wherein the memory member structure in at least one of the at least two branches is activatable simultaneously or after the actuating of the sliding sleeve, and a first branch assumes a shape as [a] the septal branch and a second branch assumes a shape as [a] the lateral branch for respectively assuming a septal position and a lateral position in one of the atrium and the ventricle of the heart.

17. (Amended) The electrode arrangement according to claim 15, wherein at least one memory member structure, in at least one of the branches, experiences a predetermined change in shape by being heated above a predetermined temperature.

19. (Amended) The electrode arrangement according to claim [13] 20, wherein the electrode lead is split into three different branches.

Excerpt from Reference: EP 0 601 328 A1

Figure 3 shows an intracardial [endocardial?] defibrillation electrode with an electrode head 17. The embodiment of this electrode head differs from the electrode head shown in Figures 1 and 2. This electrode head 17 comprises a number of leg-shaped parts 18, 19 that are connected to the conductor 10 (not shown herein) of the electrode cable 4 and function as defibrillation surfaces. For reasons of clarity, Figures 3 and 4 only show two leg-shaped parts 18, 19. The electrode head 17 preferably can be provided with a higher number of such parts 18, 19 that are attached evenly distributed on the distal end of the electrode cable. The material and form of these leg-shaped parts 18, 19 are such that they are positioned at least in part against each other, provided they are in a passive position, shown in Figure 3. A balloon-type part 20 that can be inflated is also attached at the distal end of the electrode cable 4, between the leg-shaped parts 18, 19, and is connected via the duct for the electrode cable 4 to the pump 7. Before a defibrillation is realized, the balloon-type part 20 is inflated in the manner as described in connection with Figures 1 and 2. Thus, the leg-shaped parts 18, 19 expand and fit themselves against the surrounding heart wall, wherein defibrillation pulses can be emitted. Owing to the fact that the inflatable part 20 can be designed to be relatively small, the pump 7 can also be relatively small. Following a defibrillation of the heart, the electrode head 17 returns to its original passive position in that the pump 7 suctions the gas or liquid out of the part 20.

According to a different embodiment of the defibrillation electrode 2, not shown herein, the movements of the leg-shaped parts 18, 19 can also be realized with the aid of

thin wire. This wire is connected via the duct 12 for the electrode cable 4 to a motor-driven roll, installed in the defibrillator 1, and can be wound onto or unwound from this roll. In that case, the wire and the motor-driven roll are intended to replace the pump 7.